JUN 1 5 2001

K011183

510(k) Summary
Advanced Surgical Concepts
Omniport Hand and Instrument Access Device

1. SPONSOR

Advanced Surgical Concepts (ASC)
Unit 4, Sunnybank Centre
Bray, County Wicklow
Ireland

Contact Person: Tanya Hoolahan
Telephone: 353 1 2864777

Date Prepared: April 17, 2001

2. DEVICE NAME

Proprietary Name: Omniport Hand and Instrument Access Device
Common/Usual Name: Endoscopic Accessory
Classification Name: Endoscopic Accessory

3. PREDICATE DEVICES

- Dexide MultAport Cannula, Reducer and Accessories (K990739)
- Omniport Hand Access Device (K002013).

4. DEVICE DESCRIPTION

The Omniport Hand and Instrument Access Device allows the surgeon to insert his/her hand and/or instruments into the abdomen during laparoscopic surgical procedures without losing pneumoperitoneum. The Omniport device maintains a gas seal between the operator's arm or instruments and the device and between the device and the incision. The Omniport can be left in position for a complete laparoscopic procedure.

5. INTENDED USE

The Omniport Hand and Instrument Access Device provides abdominal access for the surgeon's hand and laparoscopic instruments during laparoscopic surgery while maintaining pneumoperitoneum.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Omniport Hand and Instrument Access Device is identical in design to the original Omniport. The only difference is that the new device is intended to provide instrument access, as well as hand access, to the abdomen during laparoscopic procedures while maintaining pneumoperitoneum. Both the Omniport device and other devices such as the Dexide MultAport Cannula and Accessories are designed to maintain pneumoperitoneum by providing a seal around instruments inserted through the device during minimally invasive laparoscopic procedures.

7. PERFORMANCE TESTING

Results from bench testing and animal testing were provided which demonstrate that the Omniport Hand and Instrument Access Device functions as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Advanced Surgical Concepts
c/o Ms. Mary McNamara-Cullinane, RAC
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K011183
Trade/Device Name: Omniport Hand and Instrument Access Device
Regulation Number: 876.1500
Regulatory Class: II
Product Code: GCJ
Dated: April 17, 2001
Received: April 18, 2001

Dear Ms. McNamara-Cullinane:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011183

Device Name: Advanced Surgical Concepts
Omniport Hand and Instrument Access Device

Indications for Use:

The Omniport Hand and Instrument Access Device provides abdominal access for the surgeon's hand and laparoscopic instruments during laparoscopic surgery while maintaining pneumoperitoneum.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011183

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)